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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,478	03/02/2004	Arjnarong Chantranukul	3020.PHM	2104

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

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02/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,478	CHANTRANUKUL ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 7, 9-11, 13-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 7, 9-11, 13-22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 12/18/07 are acknowledged.

2. Claims 2-3, 5-6, 8, 12 and 23 were cancelled.

3. Claims 1, 4, 7, 9-11, 13-22 and 24-26 are included in the prosecution.

Response to Arguments

Objection to the Specification

4. In light of applicant's corrections of the informalities in the specification, the objections to the specification are withdrawn.

Rejection of claims 1-19 and 23-25 under 35 USC § 103(a)

5. Applicant's arguments, see Page 9, filed 12/18/07, with respect to the rejection of claims 1-19 and 23-25 under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Winston et al. (US 5,342,626), in further view of Chang et al. (US 5,190,927) have been fully considered but are not persuasive.

Applicant argues that Gilleland does not disclose or suggest the specific combination of high acyl gellan gum and low acyl gellan gum as found in the instant claims. Applicant argues that the polymer composition of Winston is different from the modified starch composition of Gilleland and there is no suggestion of combining (Gilleland) with Winston to suggest the claimed soft shell capsule comprising the composition blend of starch, plasticizer and two acyl gellan gums (one with high acyl content and one with low acyl content). Applicant argues that the composition of Chang is quite different from both Gilleland and Winston, and the composition of Chang is used

to prepare elastic gels and not films or soft shell capsules. Applicant argues that there is no teaching or suggestion of combining or how to combine Gilleland, Winston and Chang to make the invention as being claimed obvious.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gilleland is used as a primary reference to provide the teaching of film-forming compositions that comprise starch derivatives, plasticizer, and hydrocolloid gum. It is noted in the office action that Gilleland does not expressly teach high acyl gellan gum and low acyl gellan gum. The supporting reference, Winston, remedies the deficiency by teaching low acetyl gellan gum and high acetyl gellan gum. This supporting reference is combined with the Gilleland reference. The motivation to combine the references is provided by the advantages of biodegradability, strength, thermal reversibility, water solubility and reduced processing time, as taught by Winston.

Since all the claimed elements are found in Gilleland, Winston and Chang, one skilled in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Therefore, the rejection of 7/24/07 is maintained.

Rejection of claims 17-18 under 35 USC § 103(a)

6. Applicant's arguments, see Page 10, filed 12/18/07, with respect to the rejection of claims 20-22 under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Liu et al. (US 6,303,290) have been fully considered but are not persuasive.

Applicant argues that the Liu reference and its teachings are quite distinct form Gilleland which involves a different system. Applicant argues that there is no suggestion of how to combine the references to make the claimed starch, plasticizer and high/low acyl gellan composition in shell capsules obvious.

This is not found persuasive because the primary reference Gilleland teaches film-forming compositions that comprise starch derivatives, plasticizer, and hydrocolloid gum. Gilleland does not expressly teach colloidal particles in the composition. Liu remedies the deficiency by teaching colloidal particles for biomolecule encapsulation. Since all the claimed elements are found in Gilleland and Liu, one skilled in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Therefore, the rejection of 7/24/07 is maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 4, 7, 9-11, 13-19, 24-25 and new claim 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Winston et al. (US 5,342,626), in further view of Chang et al. (US 5,190,927).

The claimed invention is a blend composition comprising a high acyl gellan gum, a low acyl gellan gum, a starch, and a plasticizer. Soft capsule shells prepared by using this blend are also claimed.

Gilleland teach film-forming compositions that comprise starch derivatives, plasticizer, and hydrocolloid gum. These compositions can "replace gelatin in edible film-forming applications such as soft and hard gel capsules" (Abstract). The starch is "selected from the group consisting of ether and ester derivatives of starch, such as hydroxypropyl, hydroxyethyl ... starch" (Col. 2, lines 6-9). The working examples include a potato starch, substituted with hydroxypropyl groups (Col. 6 – Col. 7, examples 1-7). Gellan gum is disclosed as a gum for the system (Col. 2, lines 12-13). The polyol glycerol is disclosed as a plasticizer (Col. 2, lines 16-18). A soft capsule shell using the starch-based composition is disclosed (Col. 2, lines 26-29). Example 4 includes a hydroxypropylated starch, gellan gum, and sorbitol as a plasticizer (Col. 6, lines 61-67). Example 6 includes a hydroxypropylated starch, carrageenan, and glycerine as a plasticizer (Col. 7, lines 7-12).

Gilleland does not expressly teach high acyl gellan gum and low acyl gellan gum.

Winston teaches a composition for gelatin-free soft capsules. A polymer composition "comprised of gellan, carrageenan and mannan gums and a process for producing flexible films for encapsulation" is disclosed (Col. 1, lines 6-10). Winston discloses various types of gellan gums, and includes low acetyl (LA) gellan gum and high acetyl (HA) gellan gum (Col. 3, lines 7-18). Glycerine is also disclosed as plasticizer in the film-forming polymeric composition (Col. 4, lines 43-45). Examples 1, 5, and 8 include LA gellan gum, and examples 2, 6, and 7 include HA gellan gum.

Chang teaches high-glyceryl, low acetyl gellan gum. The gellan gum used is "a partially deacylated gellan gum, having about 3-12%, preferably 4-19%, and more preferably 6-9.5% O-glyceryl groups, and less than 1% O-acetyl groups, preferably zero O-acetyl groups, which is capable of forming elastic gels having low brittleness" (Col. 1, lines 37-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film-forming compositions with starch, plasticizer, and gellan gum, as suggested by Gilleland, and combine it with the high acetyl gellan gum and low acetyl gellan gum comprising composition, as taught by Winston, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the composition taught by Winston has the advantages of "biodegradability, strength, thermal reversibility, water solubility and reduced processing time" (Winston, Col. 3, lines 2-6). Gilleland teaches that, "the presence of gum increases the rate of film

formation and enhances film strength" (Gilleland, Col. 2, lines 63-65). Furthermore, the composition is "a simple, cost effective, dependable, intrinsically safe, Kosher, and efficient means for replacing the gelatin used in soft gel capsule compositions" (Gilleland, Col. 3, lines 44-48).

Regarding instant claim 1, the limitations of a high acyl gellan gum and a low acyl gellan gum would have been obvious to one skilled in the art over the low acetyl (LA) gellan gum and high acetyl (HA) gellan gum taught by Winston (Col. 3, lines 7-18). One skilled in the art would use gellan gum based on the teaching of Gilleland and would use HA gellan gum and LA gellan gum based on the teaching of Winston in order to manipulate the softness of the capsule shell.

Regarding instant claims 2 and 3, the limitations of the high acyl gellan gum with more than 40% acetyl and more than 45% glyceryl residual substituents and of the low acyl gellan gum with less than 25% acetyl and less than 15% glyceryl residual substituents would have been obvious to one skilled in the art given the high-glyceryl, low acetyl gellan gum teaching of Chang. During the process of routine optimization of making a film-forming composition, one skilled in the art would use various gellan gums (with varying levels of acetyl and glyceryl residues) in order to achieve the desired film strength and consequently, capsule strength. The recited percentages of the acetyl and glyceryl substituents would have been obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 4-8, the recited percentages of the high acyl gellan gum and the low acyl gellan gum would have been obvious because during the process of

routine experimentation, one skilled in the art would vary the levels and ratios of the gellan gum components (high acyl gellan gum: low acyl gellan gum) in order to optimize the tensile strength and stability of the film-forming composition. Chang teaches that low levels of acetyl groups in the gellan gum allow the production of elastic, non-brittle gels (Chang, Col. 1, lines 47-50). Therefore, one skilled in the art can modify the brittleness or elasticity of the film formed by combining starch and plasticizer with the gellan gum by modifying the levels and ratios of HA gellan gum and LA gellan gum.

Regarding instant claims 9-13, and 25, the limitation of amylase containing starch would have been obvious to one skilled in the art given the examples of modified starches taught by Gilleland including, "corn, waxy maize, high amylose corn" (Col. 4, lines 7-12). Gilleland also teaches "hydroxypropyl, hydroxyethyl … starch" (Col. 2, lines 6-9).

Regarding instant claims 14-16, the percentages of the starch in the composition would have been obvious to one skilled in the art because during the process of routine experimentation, one skilled in the art would vary the level of starch in order to optimize the tensile strength and stability of the film-forming composition.

Regarding instant claims 17-19, the limitation of glycerin as a plasticizer would have been obvious to one skilled in the art given the use of glycerin as a plasticizer in the composition taught by Gilleland (Col. 7, lines 7-12). The percentage range of glycerin in the composition would have been obvious to one skilled in the art because during the process of routine experimentation, one skilled in the art would vary the level

of glycerin in order to optimize the tensile strength and stability of the film-forming composition.

Regarding instant claims 23-25, the limitations of the capsule shell composition would have been obvious to one skilled in the art over the soft gel film and capsule composition taught by Gilleland. The components of the composition, gellan gum, starch, and plasticizer are taught by Gilleland. The percentages and ratios of the HA gellan gum and LA gellan gum would be obvious variants as part of routine experimentation.

Regarding instant claim 26, the limitation of the water fluidity of the starch would have been obvious to one skilled in the art over the hydroxypropyl derivatives of starch and waxy starches of corn taught by Gilleland (Col. 2, lines 6-9 and Col. 4, lines 29-34). One with ordinary skill in the art would be able to determine the water fluidity of the starch and would vary the starch component in the composition based on the desired attributes of the capsule such as capsule hardness and stability.

9. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Liu et al. (US 6,303,290).

The teaching of Gilleland is stated above.

Gilleland does not expressly teach colloidal particles in the composition.

Liu teaches encapsulating "proteins into transparent, porous silica matrices by an alcohol-free, aqueous, colloidal sol-gel process" (Abstract). The "feasibility of using colloidal particles, especially using very fine particles ... for biomolecule encapsulation ... was proven ..." (Col. 11, lines 14-18).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film-forming compositions with starch, plasticizer, and gellan gum, as suggested by Gilleland, and combine it with the colloidal particles for encapsulation, as suggested by Liu, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because colloidal particles are well known and are generally included in compositions of tablets, capsules and other solid dosage forms.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-

9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615